

**Appendix 1**



15/02/2010 Macrolane is a trademark of Q-Med AB



**INFORMATION FOR YOUR RADIOLOGIST**

Ms/Mrs. \_\_\_\_\_ was treated with Macrolane™.

Macrolane VRF20 & VRF30 (manufactured by Q-Med AB, Uppsala, Sweden) is approved in the EU for breast enhancement, volume restoration and contouring of body surfaces.

Macrolane VRF20 & VRF30 are NASHA™ gels and as such consist of stabilized sodium hyaluronate (hyaluronic acid) of non- animal origin (20 mg/ml) and phosphate buffered saline at pH 7. Macrolane is biodegradable and it contains approximately 2% hyaluronic acid (w/w) and 98% (w/w) water. The rate of degradation of Macrolane varies between individuals and clinical studies show that the complete degradation process would take 12 to 24 months or longer.

Macrolane is an injectable viscoelastic gel. Such gels have been used for many years as fillers to treat wrinkles. As Macrolane is implanted by injection, both large coherent deposits and small deposits of gel can be present. Macrolane is usually injected below the mammary gland and above the pectoral muscle but in some patients the product is placed underneath the pectoral muscle in order to achieve good results.

Clinical studies show that Macrolane is detectable on mammography, ultrasound examination and MRI examination of the breasts. A recent clinical study indicates that the presence of Macrolane may affect the diagnostic quality of parts of the mammograms performed for breast cancer screening purposes. Ultrasound can be used if complementary examinations are needed. Pre-implant mammograms may also facilitate post-treatment mammography evaluations. The following figures illustrate the appearance of Macrolane on mammography, MRI and ultrasound.

For more information, please also see [www.macrolane.com](http://www.macrolane.com)



FIRST TREATMENT

The following volume of Macrolane was injected:

	Volume in right breast	Volume in left breast
Under the mammary gland	ml	ml
Under the Pectoralis muscle	ml	ml

Date of treatment: \_\_\_\_\_

Mammography pre-treatment  Yes  No    Ultrasound pre-treatment  Yes  No

Treated by Doctor: \_\_\_\_\_

Telephone number to Doctor: \_\_\_\_\_

RETREATMENT

The following volume of Macrolane was injected:

	Volume in right breast	Volume in left breast
Under the mammary gland	ml	ml
Under the Pectoralis muscle	ml	ml

Date of treatment: \_\_\_\_\_

Mammography pre-treatment  Yes  No    Ultrasound pre-treatment  Yes  No

Treated by Doctor: \_\_\_\_\_

Telephone number to Doctor: \_\_\_\_\_

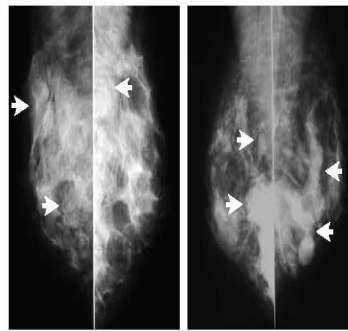


Figure 1. Twelve-month mammograms (MLO projection) from two, representative study participants. The arrows indicate the location of implanted HA gel.

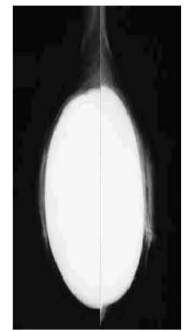


Figure 2. Mammograms (MLO projection) of breasts augmented with silicone – the opaque implants are clearly visible.

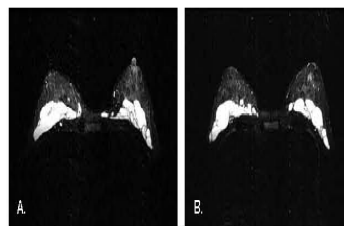


Figure 3. MRI scans performed at 3 months (A) and 12 months (B) following implantation of HA gel (both scans are transverse STIR sequences from the same patient).

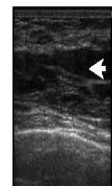


Figure 4. Ultrasound image 6 months after treatment. Pictures courtesy of Dr. Millefiori.

